

UNITED STATES PATENT AND TRADEMARK OFFICE

BEFORE THE PATENT TRIAL AND APPEAL BOARD

IMPERATIVE CARE, INC.,
Petitioner,

v.

INARI MEDICAL, INC.,
Patent Owner.

Case No. IPR2024-01157
U.S. Patent No. 11,697,011

PATENT OWNER'S PRELIMINARY RESPONSE

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EXHIBIT LIST

	Petitioner's Exhibits
Exhibit	Description
1001	U.S. PATENT NO. 11,697,011 ("the '011 Patent")
1002	'011 Patent Prosecution History Excerpt
1003	Expert Declaration of Troy Thornton
1004	Resume of Troy Thornton
1005	U.S. Patent Publication US 2003/0225379 A1 to Schaffer et al. ("Schaffer")
1006	U.S. Patent Publication US 2003/0116731 A1 to Hartley ("Hartley")
1007	U.S. Patent No. 9,980,813 B1 to Eller ("Eller")
1008	Drawings Submitted During Prosecution of U.S. Patent Application No. 10/371,190 dated June 18, 2003
1009	U.S. Patent No. 5,429,616 to Schaffer ("Schaffer '616")
1010	U.S. Patent Publication US 2011/0144592 A1 to Wong et al. ("Wong")
1011	U.S. Patent Publication US 2015/0173782 A1 to Garrison et al. ("Garrison")

	Patent Owner's Exhibits
Exhibit	Description
2001	Declaration of Paul J. Zalesky
2002	Merriam-Webster's Collegiate Dictionary (11 th ed. 2014)
2003	New Oxford American Dictionary (3 rd ed. 2010)
2004	U.S. Patent Application Publication No. 2018/0193043
2005	Deposition Transcript of Troy Thornton (September 30, 2024)

I. INTRODUCTION

Petitioner has failed to demonstrate a reasonable likelihood that it would prevail with respect to the patentability of any one of Claims 1-9 of the '011 Patent challenged in the Petition. The following response addresses Grounds 1-5 as applied to Claim 1. Claims 2-9 depend either directly or indirectly from Claim 1 and are patentable over Grounds 1-5 for the same reasons as set forth herein with respect to Claim 1.

The '011 Patent discloses a “garrote valve” that “provides convenient, single-handed operation [that] allows the user to easily and quickly swap different tools being used through the valve without compromising hemostasis and therefore simplifying the procedure.” EX1001, 5:54-60. The '011 Patent's garrote valve is useful in many applications including, for example, thrombectomy procedures that use large-bore catheters and require application of significant pressure differentials using an applied vacuum. EX2001, ¶¶34-36; EX1001, 5:65-66 (“vacuum aspiration”); 16:21-44 (“embodiment of a thrombectomy system”). A person of ordinary skill in the art (“POSITA”) would understand that the valve recited in Claim 1 prioritizes user control, allowing for single-handed operation while maintaining the integrity and seal of the catheter system to minimize dangerous patient blood loss, which is important to doctors and critical to patient health.

Regarding Ground 1, Petitioner has failed to satisfy its burden that Schaffer anticipates Claim 1 because Schaffer does not disclose a “filament” as claimed. The plain and ordinary meaning of the term “filament” is “a thin, flexible length of material formed by one or more strands of material.” *See, e.g.,* Merriam-Webster's Collegiate Dictionary at 467 (11th ed. 2014) (“filament: a single thread or a thin flexible threadlike object, process, or appendage.”). The '011 Patent confirms that the filament is flexible in accordance with that plain meaning, describing that the filament acts as a garrote forming a loop that decreases in size as the ends are pulled apart, which is only possible if the filament is flexible. EX1001, 13:38-41 (“a diameter or size of the loop 604, or of the loops 704, 706 can decrease when the constricting mechanism 141 is moved from the second configuration to the first configuration.”). Even Petitioner's own expert has conceded in the corresponding district court litigation that his proposed construction for “filament,” which does not include flexibility, is incomplete. EX2005, 123:1-3. (“in the ordinary meaning of filament, it has flexibility.”).

That admission is fatal to Petitioner's Ground 1, which depends on an overbroad and illogical construction of “filament” that Petitioner admits is “more broad[] than the plain and ordinary meaning” of filament. Paper 1 at 13. Despite the admission, Petitioner presents no arguments that the patentee made the clear and unambiguous disclosures needed to act as its own lexicographer for the term.

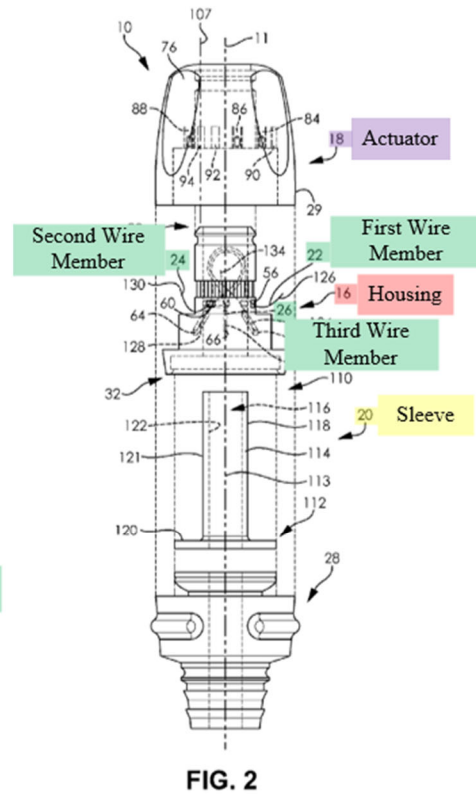
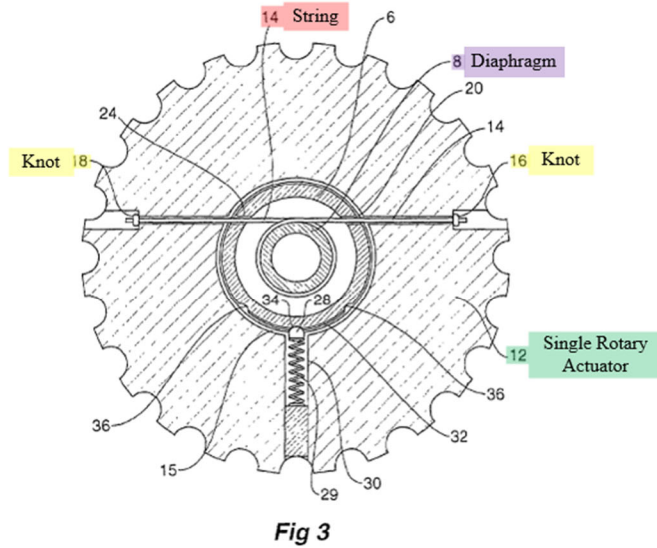
Thorner v. Sony Computer Ent. Am. LLC, 669 F.3d 1362, 1365-66 (Fed. Cir. 2012).

Petitioner's construction also contradicts the '011 Patent's disclosure, which confirms that a filament is flexible (exactly its plain meaning). Once "filament" is properly construed, Ground 1 fails because Schaffer's U-shaped actuating members are rigid.

Regarding Grounds 2-4, Petitioner asserts that it would be obvious, either over Schaffer alone or further in view of Hartley or Eller, to replace Schaffer's rigid U-shaped actuating members with string or wire. But, Petitioner cannot demonstrate a reasonable likelihood that it will prevail on the merits because a POSITA would not have been motivated to replace Schaffer's rigid U-shaped actuating members 55 with a filament. EX2001, ¶¶89-100. Petitioner's purported motivation to modify Schaffer is based on an incorrect understanding of Schaffer's disclosure. Petitioner concedes that Schaffer's U-shaped actuating members (the alleged filament) are rigid, asserting that when constricting a lumen, Schaffer's U-shaped actuating members 55 would form "small gaps" and that a "flexible string would not suffer from this potential issue because the string encircles the central lumen and precisely conforms to the diameter of the inserted devices." Paper 1 at 36. Indeed, Petitioner relies on the fact that Schaffer's U-shaped actuating members 55 are rigid to argue that their rigidity causes gaps and a poor seal as the motivation to modify Schaffer by replacing its rigid members with the string of Hartley or wire of Eller. *Id.* at 32.

But, Petitioner ignores Schaffer's disclosure of a gelatinous "seal member 165" that, in conjunction with Schaffer's rigid U-shaped actuating members 55, eliminates any gaps and forms a "nearly fluid/gas tight seal under very light compression." EX1005, ¶59. In other words, Petitioner's purported motivation to make the modification proposed in Grounds 2-4, to eliminate gaps and remedy a supposedly poor seal, ignores Schaffer's express disclosure that no such gaps are formed. Because Schaffer's valve does not result in gaps, the formation of gaps cannot serve as a motivation to modify Schaffer. Moreover, Schaffer's rigid actuating members are central to Schaffer's disclosed principle of operation, including forcible disengagement, simple manufacturing methods, and durability. EX2001, ¶¶101-108. Thus, a POSITA would not have been motivated to modify Schaffer, either alone or in view of Hartley or Eller, as Petitioner proposes.

Regarding Ground 5, Petitioner's proposed combination of Hartley and Eller fails because neither Hartley nor Eller disclose an "actuator [that] comprises a first member coupled to the first end of the filament and a second member coupled to the second end of the filament" as expressly recited in Claim 1. Instead, the alleged filament in both references is coupled to a *single* one-piece rotary actuator. EX1006, ¶31; EX1007, 12:52-58.



In Hartley, as shown in Figure 3 (above, left), both ends of a string 14 are coupled to a single rotary actuator 12. EX1006, ¶31 (“A string 14 is mounted into the rotary actuator with a knot 16 at one end and then passes through [various apertures] before being fixed by knot 18 again in the rotary actuator.”). And in Eller, as shown in Figure 2 (above, right), a single end of wire member 22 is coupled to the single rotary actuator 18, and the other end of wire member 22 is attached to the housing, not the actuator at all. EX1007, 12:52-58. Accordingly, even if a POSITA did combine Hartley and Eller—one would not—that combination does not disclose an “actuator [that] comprises a first member coupled to the first end of the filament

and a second member coupled to the second end of the filament” as expressly recited in Claim 1.

For the foregoing reasons and the additional reasons set forth herein, Patent Owner respectfully requests that the Petition be denied.

II. BACKGROUND

A. Overview of the '011 Patent

The '011 Patent explains that while “traditional hemostasis valves are greatly beneficial for intravascular access, they have some drawbacks. For example, some valves may not seal adequately for all interventional applications or tools, and/or the operation of some valves may be complicated for operator use.” EX1001, 1:48-52. The '011 Patent addresses those drawbacks by providing a hemostasis valve that provides for easy one-handed operation and a strong seal around a variety of different-sized instruments, both of which are important for hemostasis valves in many applications, including for use with aspiration in large-bore thrombectomy systems, an embodiment of the '011 Patent. EX2001, ¶33; EX1001, 16:20-44 (incorporating, *e.g.*, U.S. Patent Application 15/498,320, which was published as US2018/0193043 (EX2004) by reference).

Specifically, the '011 Patent discloses that “[t]he present disclosure relates to a valve that can be used as a hemostasis valve. This valve, also referred to herein as a garrote valve, can seal with or without a tool extending through the valve.”

EX1001, 5:51-54.¹ The design and functionality of this hemostasis valve enables medical professionals to operate the valve with one hand while maintaining a robust seal to prevent blood loss during procedures. EX2001, ¶34; EX1001, 5:51-65. The design enables such ease of use while maintaining an effective and strong seal, for example, under a pressure differential caused by vacuum during aspiration thrombectomy procedures. EX2001, ¶35; EX1001, 1:61-2:10, 4:1-10, 5:5-19, 5:51-6:2, 16:20-44.

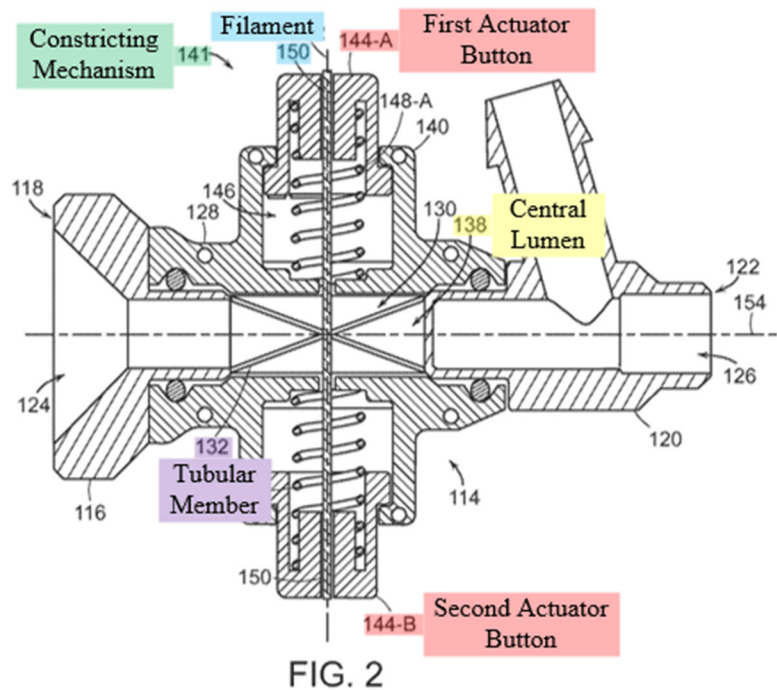
In particular, the design allows for quicker and more effective sealing of large-bore catheters for thrombectomy in large veins and pulmonary arteries, such as for treating deep vein thrombosis or pulmonary embolism. EX2001, ¶¶34-36. The hemostasis valve can be a component of a delivery system that includes a catheter. EX1001, 6:21-25. A catheter can include a shaft, identified as an elongated sheath, that has a proximal end connecting to the valve and a distal end. *Id.* at 6:25-30. The shaft defines a catheter lumen that extends from the proximal end to the distal end. *Id.* at 6:30-32. The catheter can be designed in various shapes and sizes and is typically constructed from biocompatible materials to allow for flexibility and accommodate a range of outer diameters. *Id.* at 6:32-42. When used with vacuum

¹ Merriam-Webster defines “garotte” to mean “an implement (such as a wire with a handle at each end) for strangulation.” EX2002, at 516.

aspiration thrombectomy, the ease of use and robust seal are particularly important. EX2001, ¶¶48-50; EX1001, 1:61-2:10, 4:1-10, 5:5-19, 5:60-6:2.

To address those issues and provide the benefits of reduced blood loss and one-handed operation, the '011 Patent discloses a new type of valve, a “garrote” valve, that includes a constricting mechanism that comprises an actuator and at least one filament that encircles the elongated member. *Id.* at 8:1-4. The actuator may be a manual button or an automated system, enabling easy one-handed use to seal effectively when needed. *Id.* at 8:5-8. To that end, the filament is designed to circumferentially constrict the elongated member, collapsing it to create a seal when the actuator is engaged, to ensure effective hemostasis during medical procedures. *Id.* at 8:8-12.

The actuator can be biased to seal. *Id.* at 8:35-37. In the first configuration, depicted in FIG. 2 below, the elongated member is collapsed or sealed, with buttons in an undepressed position. *Id.* at 8:37-43. Springs bias the buttons towards the first configuration. *Id.* at 8:43-53. The springs can be of various types, such as compression or tension springs. *Id.* This design ensures the mechanism remains in a predetermined state (sealed or open) based on the biasing force applied by the springs. *Id.*



B. Claims

Claim 1 of the '011 Patent recites:

A valve, comprising:

a tubular member defining a lumen configured to slidably receive a catheter;

a constricting mechanism including at least one filament and an actuator coupled to the filament, the filament comprising a first portion extending around at least a portion of the tubular member and a second portion having a first end extending from the first portion in one direction and a second end extending from the first portion in another direction, and the actuator comprises a first member coupled to the first end of the filament and a second member

coupled to the second end of the filament, wherein the first member and the second member of the actuator are moveable between (a) a first position wherein the filament circumferentially constricts the lumen to create a seal and (b) a second position wherein the filament is moved to at least partially open the lumen; and

a biasing system configured to bias the first member and the second member to the first position.

A POSITA would understand that the innovative hemostasis valve design of Claim 1 significantly enhances the sealing capability of the catheter lumen compared to previous valves in the art, particularly around tools of varying shapes and sizes, while simplifying operator use at the same time. EX2001, ¶¶48-50. Specifically, the garrote or “constricting mechanism” of Claim 1 includes “at least one filament and an actuator coupled to the filament.” The “filament” further comprises “a first portion extending around at least a portion of the tubular member” and a “second portion having a first end extending from the first portion in one direction and a second end extending from the first portion in another direction.” The actuator comprises two distinct members, namely, “a first member coupled to the first end of the filament and a second member coupled to the second end of the filament.”

The '011 Patent defines what is meant by the “first end” and “second end” of the filament, explaining that “[t]he filament 150 can comprise a single filament 150

having a first end 600 and a second end 602 as shown in FIG. 6.” EX1001, 12:58-60; EX2001, ¶41.

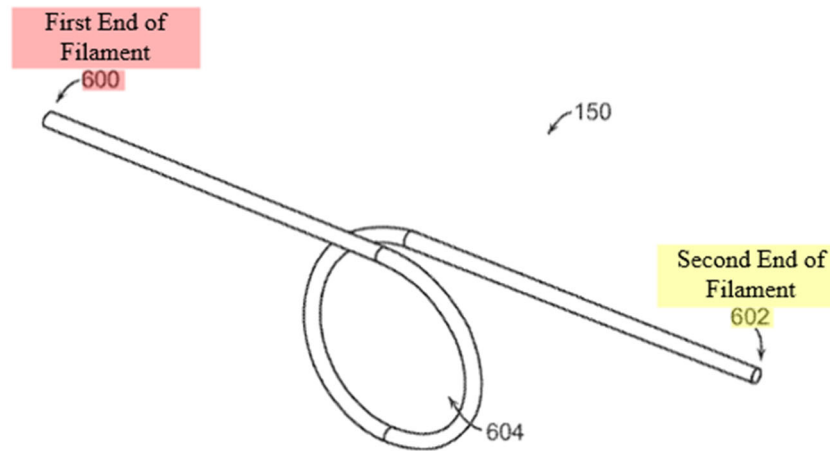
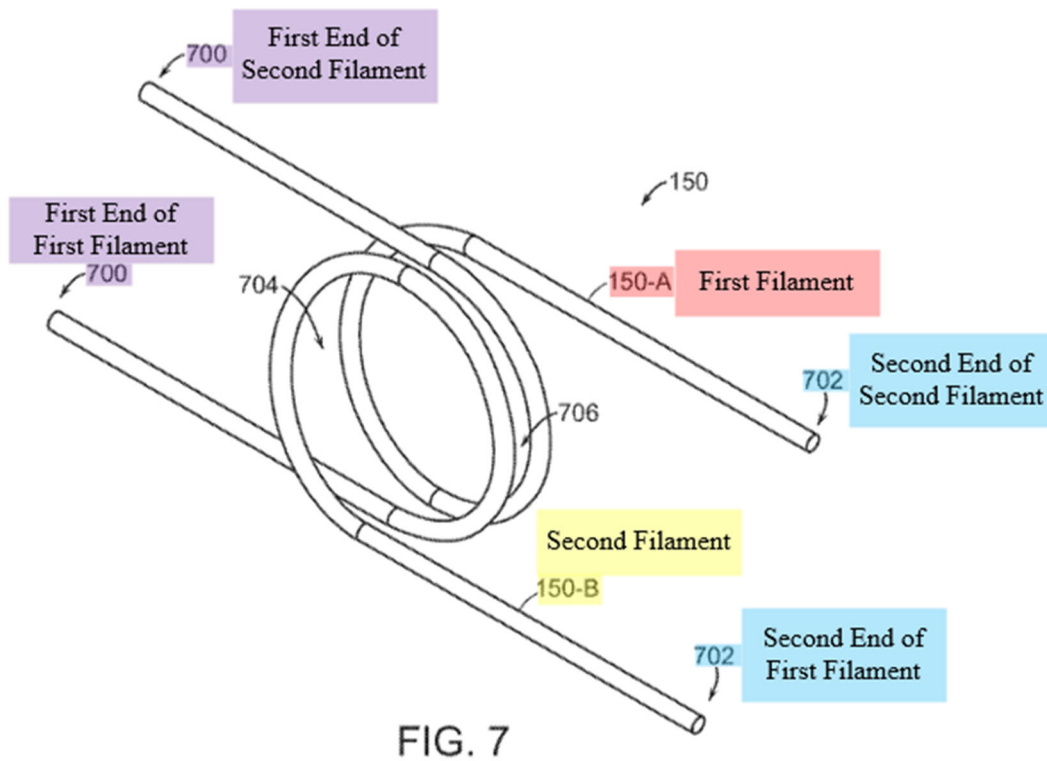


FIG. 6

And, referring to Figures 6-9, the '011 Patent further explains that “[i]n embodiments in which the filament 150 comprises multiple filaments, each of the multiple filaments can have a first end 700 and a second end 702.” *Id.* at 13:6-28. In other words, in some embodiments, a filament “can comprise multiple filaments” (*Id.* at 13:6-7), but in those embodiments, just like in embodiments comprising a single filament, reference to the first end and a second end of the filament means a first end and second end of a single continuous filament. EX2001, ¶¶42-44. That configuration is depicted in Figure 7 below:



So, the limitation of Claim 1 that the “filament” further comprises a “second portion having a first end extending from the first portion in one direction and a second end extending from the first portion in another direction” requires a single continuous filament with a “second portion having a first end extending from the first portion in one direction and a second end extending from the first portion in another direction.” EX2001, ¶¶41-47.

Petitioner’s assertion that Claim 1 includes multiple filaments that can collectively have a first end 700 and a second end 702 (Paper 1 at 11-12) rather than a single continuous filament having a first and second end is based on an obvious

typographical error in Figures 8 and 9 that is clear to a POSITA on the face of the '011 Patent and is contrary to law.²

First, as explained above, the '011 Patent expressly refers to Figures 7-9 and recites that for embodiments where the filament comprises multiple individual filaments, reference to a first end and second end of the filament means the first and second end of a single continuous filament. EX1001, 12:56-64. Based upon that disclosure, a POSITA would readily and immediately recognize that the portions of Figures 8 and 9 relied upon by Petitioner are obvious typographical errors. EX2001, ¶¶45-47.

Second, the Federal Circuit has held that while “claim language that introduces a claim element using an indefinite article and further defines the element with subsequently recited functionality ... may allow for more than a single instance of the claim element, it may nonetheless require that a single instance of the element

² The Board may correct an obvious typographical error if “(1) the correction is not subject to reasonable debate based on consideration of the claim language and the specification and (2) the prosecution history does not suggest a different interpretation of the claims.” Final Written Decision, *Beabel Education, Inc. v. Achieve3000, Inc.*, IPR20121-01169, 2023WL24133 at *4 (PTAB January 3, 2023) (interpreting claim terms to account for obvious typographical error).

be capable of performing all the recited functionality.” *Salazar v. AT&T Mobility, LLC*, 64 F.4th 1311, 1317 (Fed. Cir. 2023) (affirming district court claim construction that claim reciting “a microprocessor” performing several functions requires a single microprocessor that performs all the recited functions). *See also In re Varma*, 816 F.3d 1352, 1362-64 (Fed. Cir. 2016) (vacating Board’s rejection of claims based upon an erroneous claim construction and remanding).

Here, while “at least one filament” does not exclude multiple single continuous filaments, at least one single continuous filament must have “a first end extending ... in one direction and a second end extending ... in another direction” and where the actuator comprises “a first member coupled to [that same] first end of the filament and a second member coupled to [that same] second end of the filament.”

C. Prosecution history

The Examiner issued a Notice of Allowance on December 14, 2022. Both Hartley and Eller, which Petitioner relies upon here, were before the examiner during prosecution. EX1001, References Cited. The examiner also considered Wong (EX1010), which like Schaffer here, includes two push button actuators and a biasing spring. EX1002, at 58-60. In the Notice of Allowance, the Examiner stated that “[t]he claims in this application have been allowed because the prior art of record fails to disclose either single or in combination the claimed medical

device/method.” *Id.* at 3. The Examiner specifically found that Hartley “fails to disclose that a biasing system configured to bias the first member and the second member to the first position.” *Id.* at 4. The Examiner found that “Wong fails to disclose a filament as required in the claimed invention” and that “one skilled in the art would not use the device of Har[t]ley to combine with Wong to produce the claimed invention.” *Id.*

D. Claim construction

In an IPR, a claim is construed “using the same claim construction standard that would be used to construe the claim in a civil action” and “in accordance with the ordinary and customary meaning as understood by a POSITA and the prosecution history pertaining to the patent.” 37 C.F.R. § 42.100(b). In *Phillips v. AWH Corp.*, the Federal Circuit explained that “words of a claim ‘are generally given their ordinary and customary meaning’” and that “the ordinary and customary meaning of a claim term is the meaning that the term would have to a person of ordinary skill in the art in question at the time of the invention, i.e., as of the effective filing date of the patent application.” 415 F.3d 1303, 1312-13 (Fed. Cir. 2005) (cleaned up). “[T]he court looks to ‘those sources available to the public that show what a person of skill in the art would have understood disputed claim language to mean.’ Those sources include ‘the words of the claims themselves, the remainder of the specification, the prosecution history, and extrinsic evidence concerning relevant

scientific principles, the meaning of technical terms, and the state of the art.” *Id.* at 1314 (cleaned up).

“To act as its own lexicographer a patentee must clearly set forth a definition of the disputed claim term other than its plain and ordinary meaning and must clearly express an intent to redefine the term.” *Kyocera Senco Indus. Tools Inc. v. Int’l Trade Comm’n*, 22 F.4th 1369, 1378 (Fed. Cir. 2022) (emphasis added). “We depart from the plain and ordinary meaning of claim terms based on the specification in only two instances: lexicography and disavowal....The standards for finding lexicography and disavowal are exacting.” *Hill-Rom Services, Inc. v. Stryker Corp.*, 755 F. 3d 1367, 1371 (Fed. Cir. 2014) (internal citations omitted).

Petitioner proposes a claim construction for a single term, “filament,” that Petitioner admits is more broad than the term’s plain and ordinary meaning. Paper 1 at 13. But, Petitioner’s proposed construction is so broad and contrary to the ’011 Patent’s disclosure that it ignores a fundamental aspect of what it means to be a “filament,” namely, that a filament is thin and flexible.

1. Filament

Claim 1 recites “a constricting mechanism including *at least one filament*.” A POSITA would understand that the term “filament” as recited in Claim 1 should be according to its plain and ordinary meaning, “a thin, flexible length of material formed by one or more strands of material.”

Petitioner's proposed construction omits the requirement that a filament is flexible, proposing that a "filament" simply means "at least 'one or more threads, lines, cords, ropes, ribbons, flat wires, sheets, or tapes.'" Paper 1 at 14; EX1003, ¶52. Despite Petitioner's admission that its proposed construction is "more broad[] than the plain and ordinary meaning" of filament (Paper 1 at 13), Petitioner does not argue that the patent acted as its own lexicographer, which requires clear and unambiguous disclosure sufficient to depart from the plain and ordinary meaning. *See Kyocera*, 22 F.4th at 1378; *Hill-Rom Services*, 755 F. 3d at 1371. And, as discussed further below, Petitioner's own expert has conceded that the plain meaning of "filament" requires both flexibility and that it be long and thin.

a. Language of the claims

First, the claim language confirms that a filament must be flexible. Claim 1 recites that "the filament circumferentially constricts the lumen to create a seal." To "circumferentially constrict," the filament must surround the entire circumference of the lumen and constrict the lumen around that circumference. EX2001, ¶¶62-63. Because a filament is flexible, it will adapt to the shape of the lumen as the lumen is constricted and thus "circumferentially constrict" the lumen, as recited in Claim 1. *Id.*

In contrast, if the filament were rigid, it could not "circumferentially constrict" the lumen because a rigid material would only constrict where the rigid material

contacts the lumen. *Id.* As the rigid material constricts the lumen, the lumen will deform, leaving gaps between the lumen and the rigid material. *Id.* Petitioner implicitly concedes that a rigid material cannot “circumferentially constrict” a lumen, asserting that Schaffer’s rigid U-shaped actuating members would form gaps when pulled against the lumen. Paper 1 at 36. In contrast, a filament, which is flexible, can change shape dynamically, allowing for better adaptability to the surface contours around the circumference of the object as it is constricted. EX2001, ¶63. Thus, a POSITA would understand that the recitation that the filament “circumferentially constricts the lumen to create a seal” requires a flexible component consistent with the plain meaning of filament. *Id.*

b. The specification

The '011 specification confirms that the term filament means “a thin, flexible length of material formed by one or more strands of material.” First, the specification recites that “the at least one filament forms a loop around the elongated member, and moving the tensioning mechanism from the second configuration to the first configuration *reduces the size of the loop* to thereby constrict the tubular member within the loop.” EX1001, 4:58-62 (emphasis added). The filament must be flexible in order to “reduce[] the size of the loop” when tension is applied to constrict the central lumen. EX2001, ¶64. The specification further describes the ability of the filament to “seal around a wide range of tool sizes and shapes, as well as multiple

tools of differing sizes simultaneously.” EX1001, 2:6-8. That the filament can create a seal around various tools—each potentially with distinct shapes and sizes—further confirms that the filament is flexible to conform to the shape of the tool.

While the specification describes the filament as comprising “a polymer, a synthetic, and/or a metal” (*Id.* at 9:10-13), that the filament can be made from materials that can be formed into rigid components does **not** redefine the term “filament” from its plain and ordinary meaning to include a rigid component. EX2001, ¶65. A POSITA would understand that flexibility is a function of both material and form. *Id.* For example, steel can be used to create a steel girder for a building, which is rigid, but steel can also be formed into long, narrow strands to produce a flexible wire or cable. *Id.* Similarly, polymers—while potentially rigid in certain configurations—can be formed into flexible strands or lines that could serve as a filament. *Id.* Thus, the material chosen to form the filament does not alter the ordinary and customary meaning of the term “filament” as understood by a POSITA. *Id.* Petitioner’s reliance solely on the material from which the filament is made ignores that the form of a component contributes to its function and properties, not merely the materials from which it is made. *Id.*

Petitioner contends that the proper construction for “filament” is “at least ‘one or more threads, lines, cords, ropes, ribbons, flat wires, sheets, or tapes’” regardless of whether or not those configurations are flexible. Paper 1 at 14; EX1003, ¶52. In

other words, Petitioner asserts that a filament is any structure that includes “at least one or more” of the recited list of structures provided in a list at column 9, lines 18-20, of the specification. But each of those configurations is consistent with the plain meaning of a filament, which must be flexible. EX2001, ¶¶65-66. Indeed, every one of “threads, lines, cords, ropes, ribbons, flat wires, sheets, or tapes” is consistent with a flexible material and does not redefine the term filament. There is no lexicographical definition in the specification, much less a clear one, that would support Petitioner’s construction. Petitioner’s improperly broad and results-oriented construction flies in the face of the claim language, specification, prosecution history, and the normal meaning of the term in the art.

c. Prosecution history

The prosecution history also supports that “filament” means “thin, flexible length of material formed by one or more strands of material.” In the Notice of Allowance dated December 14, 2022, the Examiner stated that Hartley discloses “at least one filament” at item 14. EX1002 at 60. Hartley refers to item 14 as a “flexible member.” EX1006, ¶34. Accordingly, the file history also demonstrates that the Examiner understood a “filament” consistently with its plain and ordinary meaning—*i.e.*, as requiring flexibility.

d. Extrinsic evidence

At deposition in related litigation, Petitioner's expert testified that the plain and ordinary meaning of "filament" includes that it is flexible. EX2005, at 116:25-118:13, 122:17-21; 123:1-15, 125:17-25. Specifically, when questioned about the meaning of the term "filament" in US Patent 11,744,691, which is a continuation of the '011 Patent, Petitioner's expert admitted that "in the ordinary meaning of filament, it has flexibility." *Id.* at 123:1-3. In other words, Petitioner's own expert agrees that the plain and ordinary meaning of "filament" requires flexibility. His testimony here that a "filament" need not be flexible is not credible.

Furthermore, Merriam-Webster's Collegiate Dictionary defines a filament as "a single thread or a thin flexible threadlike object, process, or appendage." EX2002 at 467. *See also* New Oxford American Dictionary, EX2003 at 644 (3rd Ed. 2010) (filament: "a slender threadlike object or fiber."). And Patent Owner's expert further agrees that the term filament as used in the '011 Patent means a "thin, flexible length of material formed by one or more strands of material." EX2005, 123:1-3.

Accordingly, the term "filament" should be construed to mean "a thin, flexible length of material formed by one or more strands of material."

E. Person of ordinary skill in the art

For the purposes of this response, Patent Owner has applied Petitioner's definition of a POSITA. That is, "[a] POSITA in September 2017 would have had

an undergraduate degree in mechanical engineering or a related engineering discipline and 2-4 years of product design or engineering experience.” Paper 1 at 13. Patent Owner reserves the right to contest this definition here or in the context of other proceedings relating to this and other related patents.

III. CLAIMS 1-9 ARE NOT ANTICIPATED BY SCHAFFER (GROUND 1)

Anticipation requires that “each and every element of the claimed invention” must be disclosed either explicitly or inherently and the “elements must be arranged or combined in the same way as in the claim” in a single reference. *In re Gleave*, 560 F.3d 1331, 1334 (Fed. Cir. 2009).

Here, Schaffer fails to disclose at least the following three limitations: a “filament,” “the filament comprising ... a second portion having a first end extending from the first portion in one direction and a second end extending from the first portion in another direction,” and “the actuator comprises a first member coupled to the first end of the filament and a second member coupled to the second end of the filament,” as recited in Claim 1.

A. Schaffer does not disclose a “filament.”

As set forth above, the term “filament,” as recited in Claim 1 of the '011 Patent, means “a thin, flexible length of material formed by one or more strands of material.” In contrast, Schaffer discloses rigid U-shaped members. Accordingly, Schaffer does not anticipate Claim 1.

Schaffer's U-shaped actuating members are rigid, not flexible. EX.2001 ¶¶70-78. Petitioner implicitly admits the point when it relies on the fact that Schaffer's U-shaped actuating members 55 are rigid (and thus would purportedly form gaps and a poor seal) as the supposed motivation to modify Schaffer by replacing the rigid members with the string of Hartley or wire of Eller. Paper 1 at 32.

Schaffer's disclosure also supports that its actuating members are rigid. Schaffer explains that its U-shaped actuating members "forcibly disengage," which requires a rigid member, when it says: "[i]n the second position ... each actuator button 261 is depressed[,] " which "allows each engaged actuating member 55 to forcibly disengage opposing outer walls 27 of the seal module 100 allowing the portion 108 of the containment structure 160 to retract to an uncollapsed configuration where gases and fluids can pass therethrough." EX1005 at ¶77. The actuating members would need to be rigid to "forcibly disengage" opposing outer walls of the seal module. EX2001, ¶72. In contrast, a "filament" cannot "forcibly disengage" because it is flexible and would deform when the actuator button is pressed and tension on the filament is reduced. *Id.* Therefore, unlike the "filament" of the '011 Patent, Schaffer's U-shaped members are rigid. *Id.*

Additionally, Schaffer's disclosed method of assembly relies on the rigidity of its U-shaped actuating members. The method of assembly disclosed in Schaffer uses two rigid U-shaped members to form an area through which a seal module can

be inserted, as follows: “Each actuator button 261 is completely compressed and held while the seal module 100 is inserted through the housing 20 and between each actuator 50.” EX1005, ¶83. Because Schaffer’s U-shaped actuating members are rigid, an opening is formed for the seal module to fit through when it is inserted through that opening. In contrast, a filament’s flexibility would result in the members collapsing and not forming an opening to insert the seal module through. EX2001, ¶77.

Finally, the method of manufacturing U-shaped members used in Schaffer supports that they are rigid. Schaffer discloses that “[t]he actuating member 55 ... is machined from aluminum.” EX1005, ¶82. A POSITA will recognize that machining aluminum would result in a rigid member. EX2001, ¶75.

Petitioner has failed to demonstrate a reasonable likelihood that Schaffer anticipates Claim 1 for that reason alone.

B. Schaffer does not disclose “the filament comprising . . . a second portion having a first end extending from the first portion in one direction and a second end extending from the first portion in another direction.”

As explained above, the ’011 Patent discloses that “in embodiments in which the filament 150 comprises multiple filaments, each of the multiple filaments can have a first end 700 and a second end 702.” EX1001, 13:9-12. Accordingly, Claim 1’s limitation of “the filament comprising ... a first end extending from the first

portion in one direction and a second end extending from the first portion in another direction” requires a single continuous filament “having a first end extending from the first portion in one direction and a second end extending from the first portion in another direction.”

Even if Schaffer's two rigid U-shaped actuating members 55 together are considered a “filament”—which they cannot be because they are rigid—Claim 1 requires that the filament has a first end and a second end and that first end and second end must extend in different directions. Because Schaffer's rigid actuating members are U-shaped, Schaffer does not disclose a “filament comprising ... a second portion having a first end extending from the first portion in one direction and a second end extending from the first portion in another direction,” as recited in Claim 1. Both ends of each U-shaped actuating member extend in the same direction, not in different directions. EX1005, ¶¶76-78. Petitioner does not allege otherwise.

Petitioner has failed to demonstrate a reasonable likelihood that Schaffer anticipates Claim 1 for that reason alone.

C. Schaffer does not disclose “the actuator comprises a first member coupled to the first end of the filament and a second member coupled to the second end of the filament.”

Claim 1 further requires that “the actuator comprises a first member coupled to the first end of the filament and a second member coupled to the second end of the filament.” Again, as explained above, the “first end” of the filament and the

“second end” of the filament refer to the first and second end of a single continuous filament even where there are multiple filaments. Thus, Claim 1 not only requires a single continuous filament “having a first end extending from the first portion in one direction and a second end extending from the first portion in another direction,” as explained above, but for that same first end and same second end that “the actuator comprises a first member coupled to the first end of the filament and a second member coupled to the second end of the filament.”

Petitioner does not allege that either of Schaffer's U-shaped actuating members satisfies that requirement. Both the first end and second end of each rigid U-shaped actuation member are coupled to the same button. EX1005, ¶¶76-78. A POSITA would understand that because the U-shaped actuating members are rigid, each would have to be coupled to a single button; otherwise the actuating members could not actuate. EX2001, ¶73.

Petitioner has failed to demonstrate a reasonable likelihood that Schaffer anticipates Claim 1 for that reason alone.

IV. CLAIMS 1-9 ARE NOT OBVIOUS OVER SCHAFFER ALONE (GROUND 2), FURTHER IN VIEW OF HARTLEY (GROUND 3), OR FURTHER IN VIEW OF ELLER (GROUND 4)

Whether “combining disclosures from multiple references, combining multiple embodiments from a single reference, or selecting from large lists of elements in a single reference, there must be a motivation to make the combination

and a reasonable expectation that such a combination would be successful, otherwise a skilled artisan would not arrive at the claimed combination.” *In re Stephan Co.*, 868 F.3d 1342, n.1 (Fed. Cir. 2017) (reversing and vacating PTAB finding of obviousness). As the Federal Circuit explained *In re Kahn*, the rationale underlying the motivation-suggestion-teaching test serves as a safeguard against the improper use of hindsight in an obviousness analysis. 441 F.3d 977, 986 (Fed. Cir. 2006).

Moreover, when there is good reason not to modify or combine references, courts find that the required motivation is missing. *E.g.*, *Medtronic, Inc. v. Teleflex Innovs. S.à.r.l.*, 69 F.4th 1341, 1348 (Fed. Cir. 2023) (affirming PTAB finding of no motivation to combine when modifying reference would render device inoperable to achieve its purpose); *Trivascular, Inc. v. Samuels*, 812 F.3d 1056, 1068 (Fed. Cir. 2016) (upholding finding of nonobviousness where “substitution would destroy the basic objective of” a key feature of the reference being modified).

Here, Petitioner fails to demonstrate a reasonable likelihood that Claims 1-9 are obvious over Schaffer, either alone or further in view of Hartley or Eller. First, Petitioner’s proposed motivation to modify Schaffer, namely, that Schaffer’s rigid actuating members result in gaps, is based on an incomplete and incorrect understanding of Schaffer’s sealing mechanism. A POSITA would understand that Schaffer’s constricting mechanism does not result in gaps. With that understanding, a POSITA cannot be motivated to modify Schaffer to remove non-existent gaps.

Moreover, a POSITA would not have been motivated to modify Schaffer as Petitioner proposes because there is good reason not to do so. Specifically, Petitioner's proposed modification replacing Schaffer's U-shaped rigid actuating members with a filament would change the fundamental principle of operation of Schaffer, preventing forcible disengagement, and would necessitate fundamental changes to how the members are manufactured (preventing machining) and how Schaffer discloses that its valve is assembled.

A. A POSITA was not motivated to modify Schaffer to arrive at Claim 1.

1. Petitioner's purported motivation is contradicted by Schaffer.

Petitioner's assertion that a POSITA would be motivated to modify Schaffer to replace the rigid U-shaped members with a filament to avoid gaps and create a better seal is directly contradicted by Schaffer's disclosure, which explains that a "nearly fluid/gas tight seal" is formed when the rigid U-shaped members of Schaffer are used. EX2001, ¶¶89-100; EX1005 at ¶¶59-60 (sealing around a variety of instrument diameters and profiles). In other words, Petitioner's purported problem in Schaffer, namely, the formation of gaps that prevent an adequate seal, is manufactured from whole cloth and ignores Schaffer's express disclosure that gaps are not formed and there is a strong seal even "under very light compression." EX1005, ¶59. Indeed, Petitioner admits that Schaffer forms a complete seal, stating,

“Schaffer discloses a hemostasis valve for use during minimally invasive intravascular procedures ‘that blocks the flow of gas or fluid completely and immediately with or without an instrument in place within the gas/fluid path.’ (Ex. 1005, [0002], [0008].)” Because Petitioner’s purported motivation to modify Schaffer is to address a problem that is not found in Schaffer, a POSITA would not be so motivated.

Specifically, Schaffer discloses that its rigid U-shaped members 55 do not result in gaps due to the inclusion of sealing member 165. EX1005, ¶59. Schaffer discloses that the valve creates a “nearly fluid/gas tight seal under very light compression,” a functionality achieved through the use of materials that “can be compared to a gelatinous substance.” *Id.* Schaffer discloses that this compliant material ensures a robust seal, even in the presence of rigid components, as it is designed to “be easily compressed upon itself or upon an inserted instrument,” due to its sticky nature and “selfclosing” properties. *Id.* Schaffer further emphasizes the effectiveness of this sealing mechanism, noting that the materials stick conclusively to themselves, providing an additional layer of assurance that no gaps will form during operation. EX2001, ¶¶89-93.

The absence of gaps due to Schaffer’s gelatinous seal member 165 is further shown in Schaffer’s Figures 16-19, reproduced below. EX2001, ¶¶91-99 (citing EX1005, ¶60).

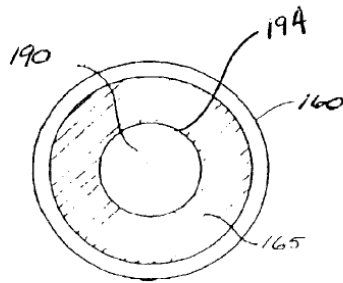


FIG. 16

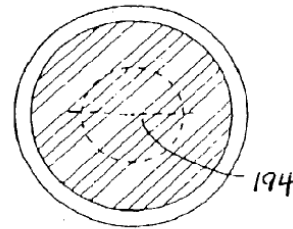


FIG. 17

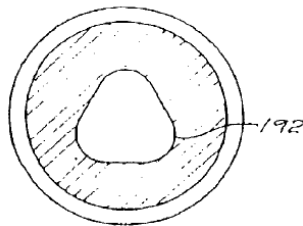


FIG. 18

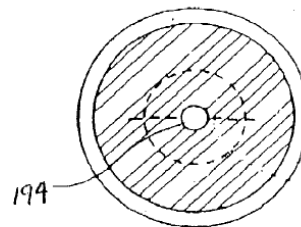


FIG. 19

Thus, a POSITA is not motivated to modify Schaffer to prevent Petitioner's purported gaps because Schaffer makes clear that its seal module and actuating members negate the possibility of gaps through the use of its compliant tubular membrane. EX2001, ¶¶93-100. Accordingly, Petitioner fails to provide any motivation to modify Schaffer as claimed.

2. Petitioner's proposed modification would change Schaffer's principle of operation without a reasonable expectation of success.

There is no motivation to modify a reference or combine prior art references where modification/combination would alter the principle of operation or would render the prior art inoperable for its intended purpose. *See Adidas AG v. Nike, Inc.*, 963 F.3d 1355, 1358-59 (Fed. Cir. 2020) (affirming lack of motivation to combine references where the proposed modification would “require the alteration of the principle of operation of [the primary reference] or would render [the primary reference] inoperable for its intended purpose.”); *Plas-Pak Indus. V. Sulzer MixPak AG*, 600 Fed.App'x. 755, 758 (Fed. Cir. 2015) (rejecting obviousness findings where the necessary alterations to a first reference would fundamentally change its “principle of operation”).

Here, a POSITA would understand that Schaffer's rigid U-shaped actuating members are necessary to “forcibly disengage” those members and for Schaffer's disclosed method of manufacture. EX1005, ¶¶80-82. As such, a POSITA would not have been motivated to modify Schaffer as Petitioner suggests.

a. Modifying Schaffer would prevent forcible disengagement.

Contrary to Petitioner's assertions, a POSITA would not replace Schaffer's rigid U-shaped actuating members 55 with a filament because such a modification would eliminate Schaffer's principle of operation: forcible disengagement. EX2001,

¶¶106-08. Schaffer discloses that when actuator buttons 261 are depressed to open its valve, the U-shaped members “forcibly disengage,” allowing the flow of gases and fluids. EX1005, ¶80. Schaffer describes the mechanics once the button is depressed by explaining that “such movement allows each engaging actuating member 55 to forcibly disengage opposing outer walls 27 of the seal module 100 allowing the portion 108 of the containment structure 160 to retract to an uncollapsed configuration where gases and fluids can pass therethrough.” *Id.* That operation requires rigid actuating members that disengage the seal module upon actuation because they are rigid. EX2001, ¶¶107-08.

For Schaffer's valve to function as intended, the actuating members must maintain their rigidity to ensure that they can effectively apply and release force. *Id.* A POSITA would understand that if Schaffer's rigid U-shaped actuating members 55 were replaced with filaments, they would not “forcibly disengage” the seal module. *Id.* Unlike rigid materials that can maintain their structural integrity under pressure, filaments are flexible and thus do not maintain their shape. *Id.* In other words, the flexible nature of a filament would cause it to bend or collapse while potentially still attached to the membrane rather than “forcibly disengage” the outer walls of the seal module. *Id.*

Thus, a POSITA would recognize that Petitioner's proposed modification to Schaffer would change its principle of operation and thus would not be motivated to make the proposed modification.

b. Modifying Schaffer would compromise its ease of manufacturing and durability.

Petitioner's proposed modification to Schaffer would compromise the durability of Schaffer's valve and complicate its manufacturing. *Id.* at ¶¶101-05. Schaffer's rigid U-shaped actuating members 55 are purposefully designed to be rigid. *Id.* ("machined from aluminum" or "machined from plastic."). That design choice provides a simple method(s) of assembly and manufacturing, and it effectively addresses Schaffer's recognized need for "a durable stasis valve that blocks the flow of gas or fluid completely and immediately with or without an instrument in place within the gas/fluid path." EX1005, ¶8.

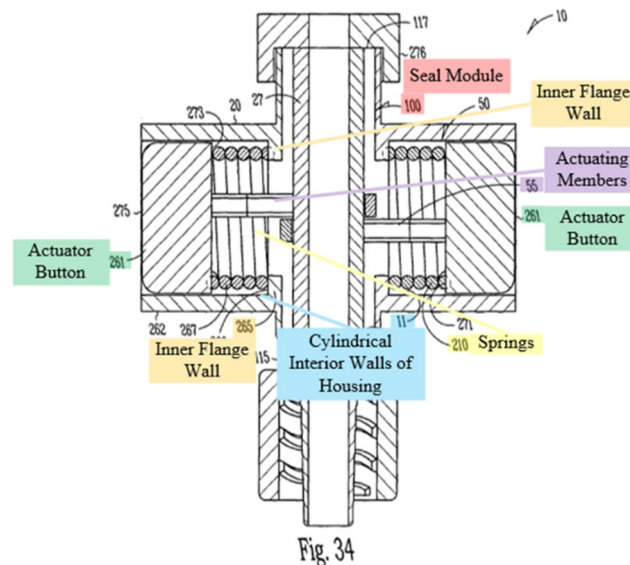
First, Schaffer discloses a method of manufacture of its valve that relies upon its U-shaped actuating members being rigid. Specifically, Schaffer discloses that its u-shaped members are machined, and that the valve is assembled by inserting the seal module "through the housing 20 and between each actuator 50" after those positions of the valve are already assembled, as follows:

[I]nserting the actuator button 261 and resilient member 267 (e.g., spring 210) into one side of the housing 20. The actuator button 261 and resilient member 267 (e.g., spring

210) are inserted into an opposing side of the housing 20. Each actuator button 261 is completely compressed and held while the seal module 100 is inserted through the housing 20 and between each actuator 50. Each actuator button is released and the cap 276 secured to the housing 20, for example, with an adhesive. Further, the connecting member 35 is snapped onto the housing.

EX1005, ¶83.

The components used in this assembly can be seen in annotated Figure 34, below, showing that in the depressed position, the rigid U-shaped actuating members are forcibly pushed open (similar to forcible disengagement) to provide a gap through which the seal module can be inserted during assembly.



A POSITA would understand that flexible actuating members, like the filament in the '011 Patent, would disrupt insertion of the seal member “through the

housing 20 and between each actuator 50.” EX2001, ¶¶104-05. Unlike the rigid actuating members 55, a filament lacks the structural integrity needed to maintain a sufficiently uniform opening for the insertion of the seal module 100 when actuator buttons 261 are depressed. *Id.* A flexible member would instead bend, deform, or collapse during this step, not allowing for the easy formation of an opening to insert the seal module as disclosed by Schaffer's assembly process. *Id.* Therefore, a POSITA would recognize that this substitution of the rigid U-shaped actuating members with the filaments of the '011 Patent is contrary to Schaffer's disclosed method of assembly. *Id.*

Petitioner ignores Schaffer's method of manufacture that relies on rigid actuating members and provides no reason a POSITA would have expected success in assembling the proposed modified valve. Petitioner's generic reliance on a POSITA's common sense based upon “extensive experience” with materials and components (Paper 1 at 32) or that a POSITA “would have possessed the skill and knowledge to adjust the shape, material, and/or dimensions of Schaffer's U-shaped actuating members” is insufficient as a matter of law. *See Arendi S.A.R.L. v. Apple Inc.*, 832 F.3d 1355, 1366 (Fed. Cir. 2016) (finding “conclusory statement is insufficient to justify a conclusion about ‘common sense’” to support obviousness and reversing PTAB finding of unpatentability).

With respect to durability, Schaffer's construction enables the valve to endure operational demands and maintain its performance and structural integrity over time. EX2001, ¶102. For example, the rigidity of the U-shaped members imparts the necessary strength and stability to prevent deformation or failure when the actuating members are actuated. *Id.* The introduction of filaments from the '011 Patent could weaken the valve's durability given the flexible nature of filaments, ultimately undermining its intended function of providing a dependable and long-lasting seal mechanism. *Id.* Regarding manufacturing, Schaffer discloses that its U-shaped members can be quickly and efficiently manufactured by means of machining (by controlled removal of material to form the desired shape) or by injection molding the same rigid materials as follows:

The stasis valve 10, in one option, is made from machining pre-existing amounts of metals and/or plastics. For example, [t]he actuating member 55 and the actuating button 261 is machined from aluminum. In another example, the actuating member 55 and the actuating button 261 are machined from plastic where the housing 20, in one option, is machined from ABS plastic. In another example, the housing 20, actuator button 261, the connecting member 35 and a cap 276 are injection molded utilizing the various material outlined above.

EX1005, ¶82.

Schaffer's standard machining methods to manufacture its rigid U-shaped members would not work well with filaments. EX2001, ¶¶103-05. Filaments deform when subjected to force during the machining process, which makes it exceedingly challenging—if not unfeasible—to achieve the precise dimensions and structural integrity required for effective valve operation. *Id.* A POSITA would recognize that filaments are ill-suited for Schaffer's straightforward manufacturing and assembly techniques. *Id.*

Therefore, a POSITA would recognize that modifying Schaffer's U-shaped members to incorporate the flexible filaments of the '011 Patent is neither practical nor beneficial and would not be motivated to do so.

B. A POSITA was not motivated to modify Schaffer in view of Hartley to arrive at Claim 1.

Combination of Schaffer with Hartley's rotational mechanisms having wire or suture filaments does not solve the fundamental issues above. Specifically, for the proposed combination, Petitioner has failed to provide motivation to modify Schaffer in view of Hartley because Schaffer's rigid U-shaped actuating members do not result in gaps as Petitioner proposes. A POSITA would also not modify Schaffer in view of Hartley because doing so would change Schaffer's principle of operation (forcible disengagement) and render inoperable Schaffer's disclosed method of manufacture and assembly.

1. Petitioner's purported motivation is contradicted by Schaffer.

As previously discussed in §IV.A.1, Schaffer's design using rigid actuating members prevents the formation of gaps without the need for a "filament." EX2001, ¶¶89-100. Schaffer discloses that its valve is designed to create a "nearly fluid/gas tight seal under very light compressions" through the use of "extremely soft and compliant and intrinsically 'sticky'" material that "exhibits a 'selfclosing' nature in that it sticks occlusively to itself," ensuring a complete and effective seal without the need for modification. EX1005, ¶59.

Given Schaffer's existing solution, a POSITA is not motivated to substitute Hartley's flexible string for Schaffer's U-shaped actuating members to "seal more effectively across a wider range of diameters for the inserted devices," as Petitioner claims. Paper 1 at 35. Schaffer's valve already addresses any concerns about sealing through the inclusion of its compliant third seal member. EX2001, ¶¶115-17. Petitioner's suggestion that gaps could form is directly contradicted by Schaffer's express disclosure. *Id.*

Therefore, a POSITA would not be motivated to modify Schaffer's U-shaped actuating members to eliminate gaps, as Schaffer's own disclosure explains that gaps are not formed.

2. Petitioner's proposed modification would change Schaffer's principle of operation without a reasonable expectation of success.

Just as is discussed in §IV.A.2, modifying Schaffer's U-shaped members with Hartley's string would change Schaffer's principle of operation. EX2001, ¶¶129-31. Schaffer's U-shaped actuating members are designed to forcibly disengage the seal module upon depression of the actuator buttons, as disclosed in Schaffer. EX1005, ¶77. A flexible string, like that of Hartley, would lack the necessary rigidity to perform that function, because it would deform or collapse instead of providing the necessary mechanical force to forcibly disengage the seal. EX2001, ¶¶129-31. Therefore, this modification would change the principle of operation of Schaffer. *Id.*

Additionally, substituting Hartley's string for Schaffer's U-shaped actuating members would introduce assembly difficulties and undermine the durability of the valve. *Id.* at ¶119. As explained above, Schaffer discloses a simple assembly process where the sealing member "is inserted through the housing 20 and between each actuator 50" after the rigid actuating members and buttons are secured in the housing. *Id.* A string would deform during assembly, making it less suitable for Schaffer's simple assembly process. *Id.* at ¶123.

Petitioner's assertion of a reasonable expectation of success for its proposed modification of where "small holes could be made in each of Schaffer's actuator buttons, and each end of the string could be threaded through the hole on the opposite

buttons and knotted on the other side” (Paper 1 at 37) does not address Schaffer’s express method of assembly relying upon rigid actuator members or that a POSITA would have a reasonable expectation of success assembling a valve with the proposed modification.

Moreover, a POSITA would readily recognize that this proposed modification would not only complicate the manufacturing process but also introduce practical challenges that could render the assembly inefficient and unreliable compared to Schaffer’s straightforward design employing rigid actuating members. EX2001, ¶¶121-25. Unlike Schaffer’s rigid U-shaped actuating members, which are “machined from aluminum” or plastic for durability and ease of manufacturing, using Hartley’s string would involve threading and knotting procedures that are inherently more difficult to execute, especially with precision and speed. *Id.* The assembly of the actuator buttons with attached strings could prove cumbersome, and the flexibility of the string could further complicate the positioning and stability of Schaffer’s seal module. *Id.* A POSITA would understand that the flexible nature of the string would impair the functionality of Schaffer’s valve as it would prevent proper tensioning when the actuators are depressed. *Id.*

Even if those challenges were overcome, Schaffer’s design is intended to provide a robust and durable solution for the sealing of catheters where its rigid

members contribute to the valve's ability to withstand wear and tear over time. *Id.* Substituting Hartley's flexible string could compromise the durability of Schaffer.

For these reasons, a POSITA would neither find it obvious nor be motivated to substitute Hartley's string for Schaffer's U-shaped actuating members, as doing so would change Schaffer's principle of operation, assembly method, and reduce durability.

C. A POSITA was not motivated to modify Schaffer in view of Eller to arrive at Claim 1.

1. Petitioner's purported motivation is contradicted by Schaffer.

Just as is discussed above in §IV.A.1, modifying Schaffer's U-shaped members with Eller's wire would fundamentally change Schaffer's principle of operation. The suggestion that substituting Eller's wire would eliminate gaps to provide a more effective seal ignores Schaffer's express disclosure that no such gaps are formed, rendering the proposed modification unnecessary. EX2001, ¶142-44. As discussed above, Schaffer discloses that its rigid U-shaped actuating members, in conjunction with a highly compliant third seal member, eliminate formation of gaps and form a "nearly fluid/gas tight seal under very light compression." EX1005, ¶59. Accordingly, a POSITA is not motivated to modify Schaffer to prevent Petitioner's purported gaps because Schaffer makes clear that its seal module and actuating members negate the possibility of gaps through the use of its compliant tubular

membrane. EX2001, ¶¶143-44. Accordingly, Petitioner fails to provide any motivation to modify Schaffer as claimed.

2. Petitioner's proposed modification would change Schaffer's principle of operation without a reasonable expectation of success.

Just as Schaffer alone or Schaffer in view of Hartley, modifying Schaffer's U-shaped members with Eller's wire would fundamentally alter Schaffer's principle of operation. EX2001, ¶¶148-49. Schaffer discloses that its U-shaped actuating members are designed to forcibly disengage the seal module upon depression of the actuator buttons. EX1005, ¶77. A flexible wire, as disclosed in Eller, would lack the necessary rigidity to perform that function and would instead deform or collapse instead. EX2001, ¶¶148-49. Therefore, this modification would change the principle of operation of Schaffer. *Id.*

Moreover, similar to Hartley's string, substituting Eller's wire for Schaffer's U-shaped actuating members would introduce significant manufacturing difficulties and undermine the durability of the valve. *Id.* at ¶147. As explained above, Schaffer discloses a simple assembly process where the sealing member "is inserted through the housing 20 and between each actuator 50" after the rigid actuating members and buttons are secured in the housing. EX1005, ¶83. A wire would deform during assembly, making it less suitable for Schaffer's simple assembly process. EX2001, ¶146.

Petitioner's assertion of a reasonable expectation of success for its proposed modification of where "the first end of the wire member would be secured to the first actuator button (first actuator member), the wire member would loop at least once around the lumen of Schaffer's valve, and then the second end of the wire member would be secured to the second actuator button (second actuator member) on the opposite side of the valve," (Paper 1 at 46) does not address Schaffer's express method of assembly relying upon rigid actuator members or that a POSITA would have a reasonable expectation of success assembling a valve according to Schaffer's disclosed method with the proposed modification.

Additionally, a POSITA would readily recognize that this proposed modification would not only complicate the manufacturing process but also introduce practical challenges that could render the assembly inefficient and unreliable compared to Schaffer's straightforward design employing rigid actuating members. EX2001, ¶¶145-47. Unlike Schaffer's rigid U-shaped actuating members, which are "machined from aluminum" or plastic for durability and ease of manufacturing, using Eller's wire would involve threading and knotting procedures that are inherently more difficult to execute, especially with precision and speed. *Id.* The assembly of the actuator buttons with attached wires would prove cumbersome, and the flexibility of the wire would further complicate the positioning and stability of the seal module. *Id.* A POSITA would understand that the flexible nature of the

wire would impair the functionality of the valve as it would prevent proper tensioning when the actuators are depressed. *Id.*

Even if these challenges were overcome, Schaffer's design is intended to provide a robust and durable solution for the sealing of catheters where its rigid members contribute to the valve's ability to withstand wear and tear over time. *Id.* Substituting Eller's flexible wire would compromise the durability of the valve and directly contradict Schaffer's stated goal of producing "a durable stasis valve." EX1005, ¶8.

For these reasons, a POSITA would neither find it obvious nor be motivated to substitute Eller's wire for Schaffer's U-shaped actuating members, as doing so would alter the valve's principle of operation, introduce significant manufacturing and assembly challenges, and reduce durability.

V. CLAIMS 1-3, 5-6, 9 ARE NOT OBVIOUS OVER HARTLEY IN VIEW OF ELLER (GROUND 5)

Petitioner's proposed combination of Hartley and Eller fails to disclose render obvious the limitations of Claim 1, from which all other claims depend. Specifically, neither Hartley nor Eller disclose that the "actuator comprises a first member coupled to the first end of the filament and a second member coupled to the second end of the filament" as expressly recited in Claim 1. Instead, each of Hartley and Eller discloses a single rotary actuator, not an actuator with a "first member" and a

“second member.” EX2001, ¶¶152-55. Moreover, a POSITA would not be motivated to modify Hartley in view of Eller as Petitioner proposes because doing so would be contrary to the purpose of Hartley. *Id.* at 160-66.

1. The combination of Hartley and Eller fails to disclose an “actuator [that] comprises a first member coupled to the first end of the filament and a second member coupled to the second end of the filament.”

Hartley specifies that each end of its string 14 is connected to a single rotary actuator 12. EX1006, ¶31. As such, Hartley fails to disclose an actuator having a “first member” and a “second member,” let alone “a first member coupled to the first end of the filament” and “a second member coupled to the second end of the filament.” EX2001, ¶¶152-55.

Similarly, Eller discloses a single rotary actuator. And, Eller's wire members have a different rotational configuration, where one end is coupled to an actuator, and the other end connects either back to itself or to a housing. *Id.* at ¶152. As noted in Eller's disclosure, the design does not have separate members for the wire ends. EX1007, 12:52-58. So, just like Hartley, Eller fails to disclose an actuator having a first member and a second member, let alone “a first member coupled to the first end of the filament” and “a second member coupled to the second end of the filament.” EX2001, ¶¶152-55.

A POSITA would recognize that the “portions of the rotary actuator” referenced by Petitioner are not first and second members as recited in Claim 1. *Id.* Specifically, these portions are not first and second members, but rather a single member. *Id.* Indeed, when describing Hartley with respect to Ground 3, Petitioner admits that the alleged filament in Hartley is attached on both ends to the same rotary actuator as follows:

As illustrated in Figure 3, Hartley's string is secured to the rotary actuator at a first end via a knot 16 and ‘then passes through an aperture 20 in the cylindrical housing 6 and then is wound preferably twice around the cylindrical diaphragm 8 ... and then passes through a further aperture 24 in the cylindrical housing before being fixed by knot 18 again in the rotary actuator’

Paper 1 at 34. Petitioner's own annotated illustration set forth at page 34 with respect to Ground 3 confirms that the alleged filament of Hartley is coupled to a single member as follows:

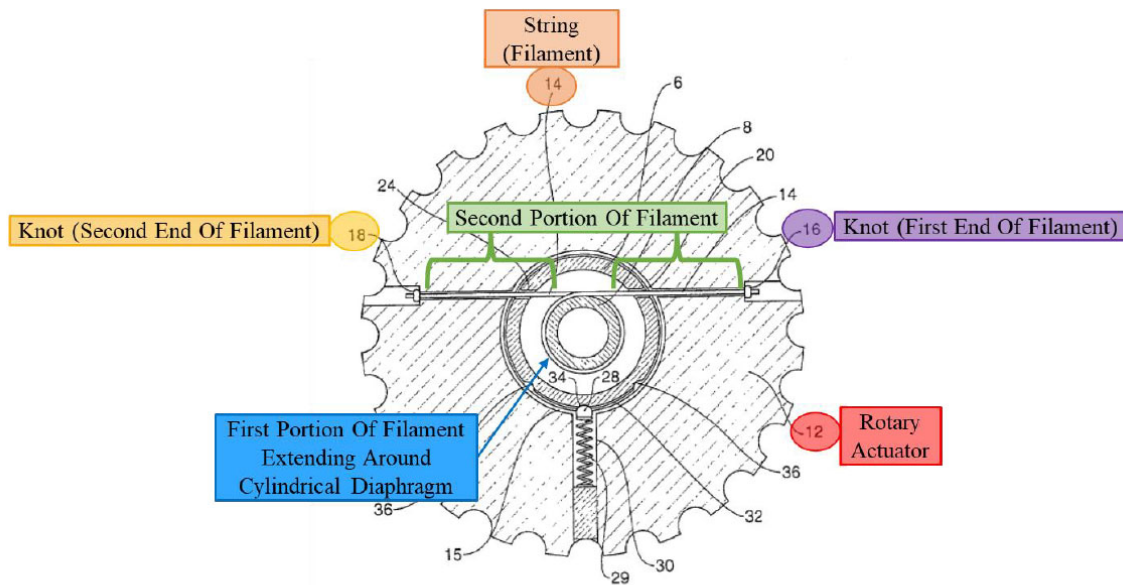


Fig 3

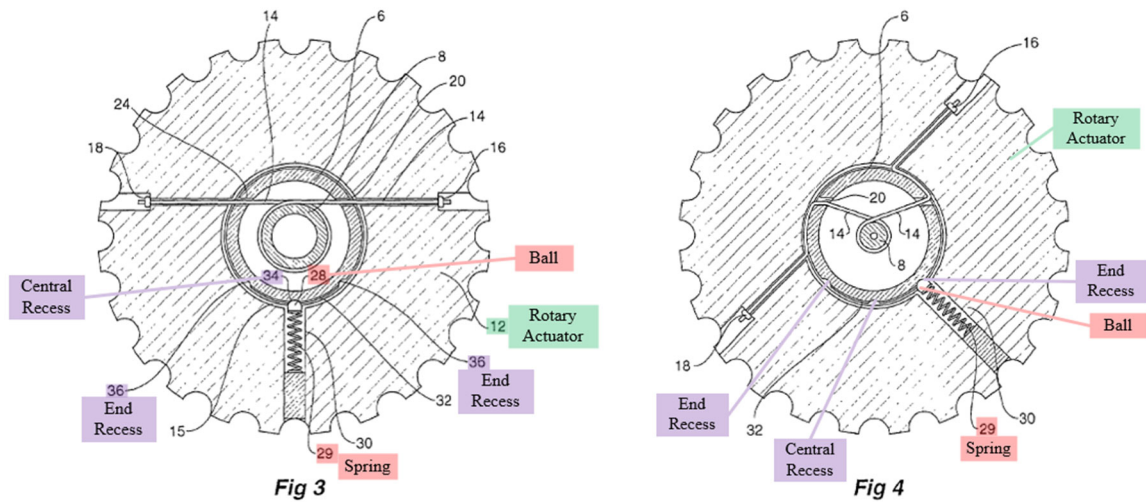
In contrast, for Ground 5, Petitioner first refers to Fig. 1, which is a cross-section of the same single rotary actuator shown in Fig. 3, this time labeling the cross-section of the single rotary actuator as having a “First Member of the Actuator” and a “Second Member of the Actuator.” Paper 1 at 73-75. But, a POSITA would understand that while the cross-section view appears to show two components, it is simply a cross-section of the single rotary actuator of Fig. 3. EX2001, ¶¶152-53.

In other words, a POSITA would understand that Figures 1 and 3 show the same single rotary actuator, not two members. *Id.* at ¶¶152-55. Petitioner does not allege that Eller discloses “actuator [that] comprises a first member coupled to the first end of the filament and a second member coupled to the second end of the filament” or that a POSITA would have modified Hartley to include that limitation. Paper 1, 73-74.

Accordingly, Petitioner has failed to meet its burden that the combination of Hartley and Eller discloses or renders obvious an “actuator [that] comprises a first member coupled to the first end of the filament and a second member coupled to the second end of the filament” as recited in Claim 1.

2. A POSITA was not motivated to modify Hartley in view of Eller because the proposed modification would change Hartley's principle of operation and render its detent system inoperable for its intended purpose.

A POSITA was not motivated to modify Hartley to include a spring as disclosed in Eller, because that modification would eliminate the object of Hartley's invention. EX2001, ¶¶156-59. Specifically, the sole object of the invention in Hartley is to “provide an access valve which can be controlled to vary the size of the aperture through the valve and be flexible so that a seal may be formed against an instrument or other object inserted through the access valve.” EX1006 ¶4. Hartley purports to satisfy that objective through a “detent arrangement.” *Id.* at ¶33. Specifically, Hartley discloses “a detent arrangement having a ball 28 loaded by a spring 29 in an aperture 30 in the rotary actuator runs in a groove 32 in the cylindrical housing 6.” *Id.* As shown in Figures 3 and 4 below, Hartley discloses a central recess 34 and end recesses 36. *Id.*



Hartley explains that the detent system provides tactical feedback as the rotary actuator is rotated and the three detents provide three different positions that correspond to three different opening sizes for the lumen. *Id.* Hartley further discloses that additional detents may be provided to allow for additional opening sizes for the lumen, as follows: “There may also be further recesses or detents between the central recess and the end recesses. The rotary actuator may be rotated in either direction to cause constriction of the constriction valve, and the detents provide tactile feel the action of the valve.” *Id.*

A POSITA would understand that modifying Hartley to include a spring, as disclosed in Eller, is not compatible with Hartley’s detent system and would render that system inoperable. EX2001, ¶¶156-59. Specifically, including Eller’s torsion spring would remove the ability to maintain various opening sizes for the lumen using the detent system. *Id.* Moreover, the pressure exerted by the torsion spring

could create significant resistance against any instruments being advanced through Hartley's valve, especially in cases where softer instruments are used. *Id.* Accordingly, a POSITA would understand that Hartley's detent system, which allows for various opening sizes for the lumen and ease of instrument advancement is necessary to Hartley's principle of operation and the express objective of Hartley's disclosure and that modification of Hartley to include a compression-biased spring would render that feature inoperable. *Id.* Petitioner fails to address Hartley's detent system and does not assert that a POSITA would remove or change that system, let alone provide motivation for such a modification.

Accordingly, a POSITA is not motivated to modify Hartley in view of Eller because Petitioner's proposed modification would change the principle of operation of Hartley's detent system and eliminate the sole "objective" of Hartley's invention.

VI. THERE IS NO GOOD CAUSE FOR A PRE-INSTITUTION REPLY

In view of the deficiencies in the Petition discussed above, Petitioner might seek to file a pre-institution reply. But there would be no good cause for a pre-institution reply. All of Patent Owner's arguments above address the merits of the Petition, and Petitioner could have—and should have—addressed these issues in the Petition itself. *See, e.g., Ontel Prods. Corp. v. Guy A. Shaked Invs. Ltd.*, IPR2020-01703, Paper 10 at 2 (Feb. 4, 2021) (denying reply for "subjects that Petitioner should have developed in its Petition").

VII. CONCLUSION

For all the above reasons, Petitioner has not met its burden of establishing a reasonable likelihood of success in showing that at least one claim is unpatentable as obvious over the cited art. Patent Owner respectfully requests that the Board deny institution.

Respectfully submitted,

Dated: October 29, 2024

By: / Joseph P. Hamilton /
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Reg. No. 51,770
Lead Counsel for Patent Owner

CERTIFICATE OF COMPLIANCE

Pursuant to 37 C.F.R. § 42.24(d), I, Joseph Hamilton, certify that **PATENT OWNER'S PRELIMINARY RESPONSE** contains 10,404 words, excluding those portions identified in 37 C.F.R. § 42.24(a), as measured by the word-processing system used to prepare this paper.

Dated: October 29, 2024

By: / Joseph P. Hamilton /
Joseph Hamilton
Reg. No. 51,770

CERTIFICATE OF SERVICE

Pursuant to 37 C.F.R. § 42.6(e), I certify that on October 29, 2024, a copy of
PATENT OWNER'S PRELIMINARY RESPONSE was served upon the be-
low-listed counsel by electronic mail:

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